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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/921,060	08/29/1997	DARRELL R. ANDERSON	012712-432	9119

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	08/921,060	ANDERSON ET AL.	
	Examin r	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13 and 16-42* is/are pending in the application.

4a) Of the above claim(s) *11-13,16-23,25-30 and 35-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,31-34,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election with traverse of the species a method of using the antibody to deplete B cells and SEQ. ID. No. 11 in Paper No. 51 and 49 is acknowledged. The traversal is on the ground(s) that are stated. Regarding the first species election, this is not found persuasive because the searching of additional species would impose an undue burden on the Examiner. Regarding the species election of SEQ. ID. No. 11 versus SEQ. ID. No. 7, the Examiner has decided to examine both species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 11-13,16-23,25-30,35-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 51 and 49.

3. Claims 24,31-34,41,42 are under consideration.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 24,31-34,41,42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "in a patient in need of such depletion" in claim 24. While the specification discloses therapeutic methods for treating B cell disorders, it does not disclose the scope of the claimed invention which encompasses use of the method to treat conditions which are not B cell disorders (such as use of B cell depletion to prevent a normal immune response against an administered antigen, etc).

There is no support in the specification as originally filed for the recitation of "merely complete B cell depletion with about 24 hours post treatment" in claim 24. Assuming that applicant intended to recite "nearly complete B cell depletion" there is also no support for said limitation in the specification as originally filed. The specification, page 15, lines 20-26 discloses a "nearly complete depletion within about 24 hours" of peripheral B cells via treatment with antiCD20 antibodies, but does not disclose a "nearly complete depletion" of B cells per se (eg. those not residing in the periphery such as B cells in the lymph nodes, etc).

There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed inventions constitute new matter).

6. Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed methods. The specification discloses use of the C2B8 chimeric antibody which contains the heavy and light chains recited in claims 31 and 32. However there is no disclosure in the specification of chimeric antibodies which contain the heavy chain of claim 31 in combination with any light chain per se wherein the antibody has the functional properties recited in the claim. Similarly, there is no disclosure in the specification of chimeric antibodies which contain the light chain of claim 32 in combination with any heavy chain per se wherein the antibody has the functional properties recited in the claim.

There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed inventions constitute new matter).

7. Claims 24,31-34,41,42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For the purposes of this rejection, it will be assumed that applicant intended to recite "nearly complete" versus "merely complete". The specification is not enabling for the claimed invention that recites administration of antiCD20 antibody wherein said antibody when administered by itself at the dosage recited in the claim causes nearly complete B cell depletion within about 24 hours post treatment infusion. The instant limitation encompasses "nearly complete" B cell depletion of all B cells in the body in all anatomical locations. However, Table II in the specification (page 53) indicates that administration of antiCD20 antibody C2B8 results in marginal B cell depletion in the lymph nodes at 7 days post treatment, followed by increased B cell depletion at day 15 post treatment. Furthermore, Reff et al. (Blood) disclose administration of a dose greater than recited in the claims (C2B8 at 1.6 or 6.4 mg/kg) wherein even 15 days after treatment lymph node depletion of 42.8%, 63.3%, 39.5% or 77.9% was seen in the four treated monkeys. These results do not demonstrate nearly complete depletion of B cells from lymph nodes. The specification is therefore not enabling for the claimed invention.

8. Claims 24,31-34,41,42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite in the recitation of "merely complete B cell depletion" because it is unclear what this term means or encompasses. Presuming applicant intended to recite "merely complete B cell depletion", said phrase would also be indefinite because there is no disclosure in the specification as to what quantitative amount of depletion constitutes "nearly depleted" and said term has no art recognized meaning.

9. Regarding the application of prior art, the prior art does not disclose a method with the limitation that the chimeric antiCD20 antibody used would have the functional property at the dosage recited in claim 24 wherein administration of said antibody would result in nearly complete depletion of B cells per se.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30

to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644